Disintegrator Products™
For a Safer World

Safeguard Medical Technologies LLC.
14200 Ellsworth Rd
Berlin Center OH, 44401
Phone (toll free): 877-797-4277
Phone (direct): 330-547-2166 Fax: 330-547-2311
Email: info@disintegratorproducts.com

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061, (HFA-305)
Rockville, MD 20852

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Reference: Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA (Issued March 2, 2001)

To Whom It May Concern:

As a manufacturer of a series of FDA approved Needle Destruction Devices (Disintegrator, Disintegrator Plus and Disintegrator Pro, PMA # 010040 with supplements S01 and S02), I am concerned that the PMA guidance document (referenced above) does not clearly differentiate between a needle "destruction" device and a simple needle "cutting" device, which generally leaves the actual needle intact but contained within the device housing.

It is my understanding that the guidance document was originally crafted to encompass devices that make the needle *unusable* by removing it from the syringe. However, according to the Merriam-Webster dictionary, the definition of "destruction" reads: 1 : the state or fact of being destroyed; 2 : the action or process of destroying something. Therefore, the term "needle destruction" would indicate that the needle should be *destroyed* and not simply *removed* or otherwise made *unusable*.

I would suggest that the guidance document be revised to clarify the difference between a Sharps Needle *Destruction* Device (product code MTV, Class 3) and a Syringe Needle Remover / Sharps Container (product code MMK, Class 2), as the current guidelines do not make this distinction.

If I may be of any assistance in this process, please feel free to contact me at any time.

Regards,

Joe Adkins, President
Safeguard Medical Technologies, LLC
d.b.a. Disintegrator Products